

### **REMARKS**

This paper is filed in response to the Office Action dated February 18, 2010. Claims 1, 4, 7, 8, 26-31, and 47 were pending in the Application, and claims 1, 4, 26-31 and 47 stand rejected. By this paper, claim 1 is amended, claims 4, 7, 8, 26-31, and 47 remain as previously presented, and new claims 48-50 are added. It is respectfully submitted that the amendments to claim 1 and the addition of claims 48-50 add no new matter to the Application; illustrative examples of support for these amendments can be found in paragraphs [0136] - [0138] and in Figs. 8A-8F of the Application, as filed. Reconsideration of the Application in view of the amendments and the following remarks is respectfully requested.

#### **Claim Rejections – 35 U.S.C. § 103**

Claims 1, 28-31, and 47 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,485,513 that issued to Fan ("Fan") in view of U.S. Patent No. 6,063,114 that issued to Nash et al. ("Nash") and U.S. Patent No. 5,749,895 that issued to Sawyer et al. ("Sawyer"); claims 4 and 26 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Fan in view of Nash and Sawyer, and further in view of U.S. Patent No. 6,482,227 that issued to Solovay ("Solovay"); and claim 27 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Fan in view of Nash and Sawyer, and further in view of U.S. Patent No. 6,428,550, which issued to Vargas et al. ("Vargas"). The Applicants respectfully

traverse these rejections. Moreover, in order to expedite prosecution of the present Application, clarifying amendments to independent claim 1 have been provided.

Claim 1

The Applicants respectfully submit that amended claim 1 is not obvious in view of any of Fan, Nash, or Sawyer, whether these references are considered individually or in combination. As amended, claim 1 recites (emphasis added):

A method for connecting a vessel to another vessel comprising:

providing a synthetic graft vessel having a first end and a second end, the second end coupled with a stent such that portions of the stent are fixedly attached to the second end of the graft vessel, wherein the stent defines an outer diameter when in an uncompressed state;

anastomosing the first end of the graft vessel to a side of an artery to yield an end-to-side anastomosis;

***inserting an introducer into a vein at a vein opening that is at a side of the vein;***

***inserting a sheath into the vein at the vein opening*** such that, when both the introducer and the sheath are in the vein, at least a portion of the introducer is within the sheath;

removing the introducer from the vein;

***inserting, after removal of the introducer from the vein, the second end of the graft vessel into the sheath such that at least a portion of the stent is advanced into the vein, wherein the vein, at a position of the vein opening, has an inner diameter equal to or smaller than the outer diameter defined by the stent when in an uncompressed state; and***

***removing the sheath from the vein such that the second end of the graft vessel is anastomosed to the vein to yield an end-to-end anastomosis in which a portion of the vein to which the second end of the graft vessel is anastomosed becomes a terminal portion of the vein.***

Accordingly, the method of claim 1 involves, *inter alia*, an anastomosis between a vein and a graft vessel that is attached to a stent. The stent is inserted into the side of a vein, which results in an end-to-end anastomosis between the vein and the graft vessel. Stated otherwise, the stent is inserted into the side of the vein, which results in the portion of the vein to which the graft vessel is anastomosed becoming a terminal portion of the vein. The Applicants respectfully submit that none of the cited prior art teaches or renders obvious such a method.

Moreover, it is respectfully submitted that the Office Action fails to set forth a *prima facie* case of obviousness with respect to claim 1. In the Office Action, it is acknowledged that the stent disclosed in Fan is used in an end-to-side anastomosis, and that it is for this very reason that “the outer diameter of the stent is smaller than the inner diameter of the vein.” Office Action, pages 4 and 5. To fill in the gaps of Fan’s teachings, it is asserted in the Office Action that “it is also well known in the art to secure two vessels together in an end-to-end anastomosis.” Office Action, page 5. Figures 3B and 4 of Sawyer are then proffered as support for this assertion, along with the generalization that in “an end-to-end anastomosis, the stent is configured to have an outer diameter that is equal to or larger than the inner diameter of the vein in order to

support/reinforce the anastomosis connection.” However, only two justifications for this combination are provided: 1) “both types of connection are well known in the art,” and 2) it has “been held that using a known technique to improve similar devices will yield predictable results.” Office Action, page 5.

The Applicants respectfully note that the first justification for combining the teachings of Fan and Sawyer – “both types of connection are well known in the art” – is essentially a “mere statement that the claimed invention is within the capabilities of one of ordinary skill in the art.” M.P.E.P. § 2143.01(IV). Even if such reasoning were assumed to be true, it “is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references.” *Id.* No such objective reason is set forth in the Office Action.

The second justification – it has “been held that using a known technique to improve similar devices will yield predictable results” – only applies in situations where “all of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods *with no change in their respective functions.*” M.P.E.P. § 2143(A) (emphasis added). This is not the case for the devices of Fan and Sawyer. As asserted in the Office Action, the purpose of the stents in Sawyer is to “support/reinforce the anastomosis connection.” Office Action, page 5. This is because, in Sawyer, a bowel is cut at two ends, these ends are positioned over the stent, and then a strip of weldable material, such as a collagen strip, is placed around the ends and welds the ends together when energy is applied thereto.

Column 9, lines 51-59. Once the welding is complete, the stent may be removed. *Id.* at lines 59-61.

The function of the stents disclosed in Fan, however, is not to “support/reinforce the anastomosis connection” so that two ends can be welded together. Rather, the function is to anchor a graft to a vessel wall and prevent dislodgement of the graft from the vessel. Column 3, lines 24-37. The distinct functions of the stents in these two references can be further appreciated from the manner in which they are used. Whereas the stents of Sawyer are configured to maintain two separate bowel pieces in a collinear arrangement (see Sawyer, FIGS. 3A-3C and 4), the stents of Fan are fashioned to join a graft to a vessel “at substantially normal incidence” (Fan at column 3, line 33 and FIG. 4).

Furthermore, as discussed in the previous Amendment filed on December 10, 2009, the Applicants reiterate that one skilled in the art would have no motivation to use the teachings of Fan to create an end-to-end anastomosis, such as that disclosed in Sawyer. In particular, modifying Fan to achieve an end-to-end anastomosis would 1) render Fan unsatisfactory for its intended purpose, and 2) change the principle of operation of this reference, in violation of M.P.E.P. §§ 2143.01 (V) and (VI), respectively. Throughout its disclosure, Fan repeatedly emphasizes that the stents therein are used for forming a “true” or “pure” *end-to-side* anastomosis, in contrast to prior art devices that “partially obstruct a vessel or divert flow . . .” Fan, col. 1, lines 45-54 and 62-63; col. 2, lines 14-18; col. 3, lines 24-37. A reference that teaches away

from obstructing a vessel or diverting flow cannot render obvious a claim that recites "an end-to-end anastomosis in which a portion of the vein to which the second end of the graft vessel is anastomosed becomes a terminal portion of the vein."

The Applicants further submit that Nash fails to remedy any of the deficiencies of Fan and Sawyer. In view of at least the foregoing discussion, the Applicants respectfully submit that a *prima facie* case has not been established with respect to amended claim 1, and further, that claim 1 is not obvious in view of any of the prior art of record, including Fan, Nash, and Sawyer. The Applicants thus respectfully request that the rejection of claim 1 under 35 U.S.C. § 103(a) be removed.

#### Claims 4, 26-31, and 47

Each of claims 4 and 26-31 depends from independent claim 1 and thus includes all of the limitations of this claim. Therefore, for at least the reasons discussed above with respect to claim 1, the Applicants respectfully submit that none of the references Fan, Nash, Solovay, and Vargas, whether considered individually or in combination, render obvious any of claims 4, 26-31, and 47. The Applicants thus respectfully request that the rejection of these claims under 35 U.S.C. § 103(a) be withdrawn.

#### New Claims 48-50

Each of new claims 48-50 depends from claim 1. Therefore, for at least the reasons discussed above with respect to claim 1, the Applicants respectfully submit that these claims are patentable.

Rejoinder

The Applicants respectfully submit that amended independent claim 1 is generic to at least withdrawn claims 7 and 8. Further, as discussed above, the Applicants respectfully submit that claim 1 is allowable. Therefore, the Applicants hereby request rejoinder of claims 7 and 8 because each of these claims depends from an allowable independent claim and requires all the limitations of the independent claim from which it depends. See M.P.E.P. § 821.04.

**Conclusion**

In view of the foregoing, it is believed that all of the pending claims are patentable in their present form and thus a Notice of Allowance for this case is respectfully requested.

The Examiner is invited to contact the undersigned attorney should any impediment to the prompt allowance of this Application remain that is susceptible to being clarified by a telephonic interview or overcome by an examiner's amendment.

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Respectfully submitted,

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